K131616
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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date

May 29, 2013

Manufacturer

Ewoo Soft Co., Ltd

S-402, 231 Pangyoyeok-ro, Bundang-Gu

Seongnam-Si, Gyeonggi-do, 463-440, Republic of Korea

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AUG 2 9 2013

United States Sales Representative (U.S. Designated agent)

Mtech Group

12946 Kimberley Ln

Houston, TX 770779

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Fax: +713-464-8880

Contact person: Mr. Dave Kim

Email: davekim@mtech-inc.net

Trade/Proprietary Name:

Ez3D-i /E3

Common Name:

Dental Imaging Software

Classification Name:

System, image processing, radiological (21CFR 892.2050, Product code LLZ, Class2)

Description:

Ez3D-i is 3D viewing software for prompt and accurate diagnosis Dental CT Images of in DICOM format with a host of useful functions including MPR, 2D analysis and 3D image reconstruction. It provides more advanced simulation functions such as Implant Simulation, Drawing Canal, and Implant Area Bone Density, etc for the benefit of effective communication between doctor and patient as well as precise treatment planning.

Ez3D-i is a useful tool for an easier diagnosis and analysis by processing a 3D image with simple and convenient user interface. Ez3D-i's main functions are;

- Effortless image adaptation through various rendering methods such as Teeth/Bone/Soft tissue/MIP
- Versatile 3D image viewing via MPR Rotating, Curve mode.
- "Sculpt" for deleting unnecessary parts to view only the region of interest.
- Implant Simulation for efficient treatment planning and effective patient consultation.
- Canal Draw to trace alveolar canal and its geometrical orientation relative to teeth.
- "Bone Density" test to measure bone density around the site of implants.
- Various utilities such as Measurement, Annotation, and Gallery, Report

Indication for use:

Ez3D-i is dental imaging software that is intended to provide diagnostic tools for maxillofacial radiographic imaging. These tools are available to view and interpret a series of DICOM compliant dental radiology images and are meant to be used by trained medical professionals such as radiologist and dentist.

Ez3D-i is intended for use as software to load, view and save DICOM images from CT, panorama, cephalometric and intraoral imaging equipment and to provide 3D visualization, 2D analysis, in various MPR (Multi-Planar Reconstruction) functions.

Predicate Device:

Manufacturer : CyberMed, Inc

Device : OnDemand3D
510(k) Number : K113543 (Decision Date – September 12, 2012)

Substantial Equivalence:

Ez3D-i described in this 510(k) has the similar intended use and similar technical characteristics as OnDemand3D of CyberMed Inc.

The model OnDemand3D is the primary predicate device. The subject device and predicate device are substantially equivalent, having the similar indications for use and functionalities like operation software, computer platform, Picture archiving and communication format, image format, image processing features, windowing, 3D image construction, image edit, measurements and manipulation. The differences are such that Ez-3D-i lacks the capability to fabricate implant surgical guides and has no functions to create orthodontic tracing analysis using 3D volume data. Both the proposed device and the predicate device are categorized in product code LLZ; equivalence between these models is evident.

Any differences between the predicate device and the proposed device are not significant since they do not raise any new or potential safety risks to the user or patient and questions of safety or effectiveness. The proposed device is equivalent in performance to existing legally marketed devices.

Technological Characteristics:

Ez3D-i is a software device that does not contact the patient, nor does it control any life sustaining devices. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed radiologists, clinicians and referring physicians as an adjunctive to standard radiology practices for diagnosis. A physician, providing ample opportunity for competent human intervention interprets images and information being presented.

Nonclinical Testing:

The complete system configuration has been assessed and tested by the manufacturer and passed all in-house testing criteria. The software validation test was designed to evaluate all input functions, output functions, and actions performed by Ez3D-i. Each operational mode and the process followed are documented in the Software Validation Report.

The validation testing verified and validated the risk analysis and individual performance results were within the predetermined acceptance criteria.

Safety and Performance Data:

- IEC 62304 Medical device software – Software life-cycle processes : 2006
- ISO 14971 Medical Devices – Application of risk management to medical device : 2007

Conclusion:

The premarket notification for Ez3D-i contains adequate information and data to determine substantial equivalence to the predicate device. The new device and predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is safe and effective. Therefore, it is our opinion that the Ez3D-i described in this submission is substantially equivalent to the predicate device.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 29, 2013

Ewoo Soft Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
12946 Kimberley Lane
HOUSTON TX 77079

Re: K131616
Trade/Device Name: Ez3D-i/E3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 09, 2013
Received: August 15, 2013

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

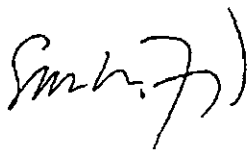
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131616

Device Name: Ez3D-i / E3

Indications for Use:

Ez3D-i is dental imaging software that is intended to provide diagnostic tools for maxillofacial radiographic imaging. These tools are available to view and interpret a series of DICOM compliant dental radiology images and are meant to be used by trained medical professionals such as radiologist and dentist.

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K131616